PCT/AT00/00040

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL OF COPIES OF TRANSLATION OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 72.2)

To:

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AUSTRIA

Date of mailing (day/month/year) 18 January 2002 (18.01.02)	
Applicant's or agent's file reference R 36247	
International application No. PCT/AT00/00040	**International filing date** (day/month/year) 17 February 2000 (17.02.00)
Applicant ALTMANN, Friedrich	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

AU,CA,CN,JP,KP,KR,NZ,US

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AP,EA,EP,AE,AL,AM,AT,AZ,BA,BB,BG,BR,BY,CH,CR,CU,CZ,DE,DK,DM,EE,ES,FI,GB,GD,GE,GH, GM,HR,HU,ID,IL,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,NO,PL,PT, RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW,OA

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See V lume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
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1211 Geneva 20, Switzerland

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Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference R 36247	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/AT00/00040	International filing date (*day/month/year*) 17 February 2000 (17.02.00)	Priority date (*day/month/year*) 18 February 1999 (18.02.99)
International Patent Classification (IPC) or national classification and IPC C12N 15/54		
Applicant		

1. This international preliminary examina... ninary Examining Authority and is transmitted to the applicant acc...

2. This REPORT consists of a total of ...

☒ This report is also accompanied b... id/or drawings which have been amended and are the basis for this ... e before this Authority (see Rule 70.16 and Section 607 of the Admin...

These annexes consist of a total of ...

4.1) bis 4.5) + 11 ... weiters # "sequence" "Eating part" .... S. Pichert

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
13 September 2000 (13.09.00)	12 June 2001 (12.06.2001)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AT00/00040

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-42, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages 1-33, filed with the letter of 26 March 2001 (26.03.2001)

☒ the drawings:

pages 1/16-16/16, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the langu... re available or furnished to this Authority in the language in which the international applica... d under this item.
These elements were av... he following language _____ which is:

☐ the language of a... f international search (under Rule 23.1(b)).

☐ the language of p... n (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

8; eingereicht am 18.5.2000

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☒ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

SEE SEPARATE SHEET

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos. _____

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box IV.3

1. The different inventions are as follows:

a) Claims 1-23 and 28-33:
Preparation of GlcNAc-α-1,3-fucosyltransferase, related products, process.

b) Claims 24-27:
Recombinant glycoproteins and related pharmaceutical compositions.

2.1 These inventions are not so linked as to form a single general inventive concept (PCT Rule 13.1) for the following reasons:

A preparation of GlcNAc-α-1,3-fucosyltransferase as per one of Claims 31 and 32 is already known (see the reasons for this objection in Box V below). The special technical feature that determines the contribution made by the first invention to the prior art is the nucleic acid which encodes the GlcNAc-α-1,3-fucosyltransferase. Claims 24-27 do not include either this feature or any corresponding technical feature. The application fails to meet the requirement of unity of invention (PCT Rule 13.1) because there is no technical relationship between the two inventions involving one or more of the same or corresponding special technical features (PCT Rule 13.2).

2.2 Despite this, a full search report was compiled for the two inventions. Since a complete international preliminary examination can be carried out without undue difficulty, the IPEA has decided to waive the request to either restrict the claims or pay additional fees.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-23, 28-30	YES
	Claims	24-27, 31-33	NO
Inventive step (IS)	Claims	1-23, 28-30 (in part)	YES
	Claims	1-33 (1-23, 28-30 in part)	NO
Industrial applicability (IA)	Claims	1-33	YES
	Claims		NO

2. Citations and explanations

1. Reference is made to the following documents:

D1: STAUDACHER E. et al.: "Functional purification and characterization of a GDP-fucose: β-N-acetylglucosamine (Fuc to Asn linked GlcNac) α-1,3-fucosyltransferase from mung beans", GLYCOCONJUGATE JOURNAL, Vol. 12, 1995, pages 780-786, XP002140246

D2: ALTMANN F.: "More than silk and honey - or, can insect cells serve in the production of therapeutic glycoproteins?", GLYCOCONJUGATE JOURNAL, Vol. 14, 1997, pages 643-646, XP002140795

D3: LEROUGE P. et al.: "N-glycoprotein biosynthesis in plants: recent developments and future trends", PLANT MOLECULAR BIOLOGY, Vol. 38, 1998, pages 31-48, XP002140796

2.1 Document D1 discloses a GlcNac α-1,3-fucosyltransferase from mung beans, characterised in that it has a pI value of around 8.5 (see D1, page 783).

D1 also discloses a process for preparing mung-bean-specific carbohydrate units from human and other vertebrate glycoproteins, characterised in that carbohydrate units including peptides from bovine fibrin (GnGn) or human IgG ($GnGnF^6$), fucose units and a GlcNAc α-1,3-fucosyltransferase are added to a substrate acceptor, with the result that

fucose in the α-1,3 position is linked to the carbohydrate unit by the GlcNAc α-1,3-fucosyltransferase (see D1, pages 781-782).

2.2 The subject matter of Claims 31 and 32 thus lacks novelty (PCT Article 33(2)) because a parameter (the pI value) is not enough to delimit a product unambiguously against the prior art (PCT Examination Guidelines, Chapter III-4.7a).

In the light of the above, the subject matter of Claim 33 also lacks novelty (PCT Article 33(2)) since the characterising technical features do not permit any distinction to be made between the process known from D1 and the process according to Claim 33.

Moreover, the applicant should note that the GlcNAc α-1,3-fucosyltransferase defined in Claims 31 and 32 (and the GlcNAc α-1,3-fucosyltransferase defined in Claim 33) cannot be novel simply because the process by which it is produced is potentially novel.

3.1 Document D2 discloses a recombinant glycoprotein (human glucocerebrosidase) and a pharmaceutical composition containing it, characterised in that the glycoprotein contains the glycans Man3GlcNAc2(Fuc) (see D2, page 645). This glycan structure is the same structure that is found in insect glycoproteins, and does not contain any α-1,3-linked fucose residues (see D2, Figure 2).

Given that a product (the aforementioned glycoprotein) cannot be novel simply because the process by which it is prepared is potentially novel, document D2 is prejudicial to the novelty of the subject matter of Claims 24-27 of the present application (PCT Article 33(2)).

3.2 Document D3 discloses a recombinant glycoprotein (the murine monoclonal antibody Guy's 13) and a pharmaceutical composition containing it, characterised in that the

Insofar as they relate to a DNA molecule with the sequence according to SEQ ID No. 1, Claims 2-7 also meet the PCT requirement of inventive step (PCT Article 33(3)).

Insofar as they relate to a DNA molecule which is 70-80% homologous to the sequence according to SEQ ID No. 1, and also insofar as they relate to hybridising and degenerated sequences, Claims 2-7 do not meet the PCT requirement of inventive step (PCT Article 33(3)) (for the reasons given in point 4.4 above).

4.6 For the reasons given in points 4.1 to 4.4 above, the products and processes according to Claims 8-23 and 28-30, which are related to the DNA molecule according to Claim 1, are novel (PCT Article 33(2)).

Insofar as they relate to a DNA molecule with the sequence according to SEQ ID No. 1, the said products and processes involve an inventive step (PCT Article 33(3)).

Insofar as they relate to a DNA molecule which is at least 50% homologous to the sequence according to SEQ ID No. 1, and also insofar as they relate to hybridising and degenerated sequences, the said products and processes do not involve an inventive step (PCT Article 33(3)).

5. The subject matter of Claims 1-33 is considered to be industrially applicable (PCT Article 33(4)).

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The following observations are made in connection with PCT Article 6.

2. The subject matter of Claims 1 and 5 is not clearly identifiable because the hybridising and washing conditions are not specified. Claims are supposed to be interpreted "giving the individual words the meaning and scope which they normally have in the relevant art, unless in particular cases the description gives the words a special meaning, by explicit definition or otherwise" (PCT Examination Guidelines, Chapter III-4.2). In this instance, a person skilled in the art would be aware that the expression "rigorous conditions" was not sufficient to allow a clear understanding of the conditions in question because the term "rigorous" gives no indication as to how such conditions can be ensured. Even expressions such as "highly rigorous", "moderately rigorous" and "with little rigourousness" would be misunderstood and would not conform to the stipulation in Chapter III-4.5 of the PCT Examination Guidelines.

3. The subject matter of Claims 16 and 17 (plants/plant cells and insects/insect cells) and of Claims 24-27 (glycoproteins), Claim 30 (a DNA molecule which encodes a fucosyltransferase) and Claims 31 and 32 (fucosyltransferase) is characterised by a production process.

   Claims relating to products which are characterised by their production processes (known as "product-by-process claims") are only admissible if the products themselves meet the requirements for patentability and if the application does not contain any other information that would allow the applicant to characterise the product

VIII. Certain observations on the international application

adequately in terms of its composition, structure or other verifiable parameters.

In this instance it would be possible to characterise the plants/plant cells and insects/insect cells and also the glycoproteins, the DNA molecule and the fucosyltransferase in terms of their technical features (the vector contained in the cells, and the amino acid or DNA sequence).

This observation also applies to Claims 21-23 and 33.